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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
ORTIZ RODRIGUEZ, CARLOS R	
ART UNIT	**PAPER NUMBER**
2125	

DATE MAILED: 08/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/679,725	WHIRLEY ET AL.	
	Examiner	Art Unit	
	Carlos Ortiz-Rodriguez	2125	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 June 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-111* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-111* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4,9,12*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 31, 41, and 52 are rejected under 35 U.S.C. 112, second paragraph.

Claim 31 and 41 recites the limitation "said anatomical feature". There is insufficient antecedent basis for this limitation in the claim.

Claim 52 recites the limitation "anatomical feature". There is insufficient antecedent basis for this limitation in the claim.

3. Claims presented in this application contain the trademark/trade name TRUEGRID, MIMICS, DYNA3D, NIKE3D and GRIZ. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 2, 3, 8, 14, 16, 17, 18, 23, 29, 31, 32, 41, 43, 52, 54, 55, 56, 68, 70, 71, 72, 84, 97, 99, 100 and 110 rejected under 35 U.S.C. 102(b) as being anticipated by Berchem et al. U.S Patent No. 5,150,304.

Regarding claims 1, 16, 31, 43, 54, 55, 70, 71, 99 and 100, Berchem et al. discloses a system for analyzing the use of medical devices comprising:

a) geometry generator that receives three-dimensional volumetric data of at least one anatomical feature and generates a geometric model of said anatomical feature (C4 L47-51);

b) mesh generator (FEA computer, abstract L8) that receives the said geometric model (abstract L9-10) of said anatomical feature (bone cavity)

and the geometric model of a medical device (joint implant prosthesis/shaft),

and generates a finite element model or mesh (abstract L9-10)

incorporating both said anatomical feature and said medical device (C2 L12-17 and C2 L35-37); and

c) stress/strain/deformation analyzer (FE/ boundary condition analysis) that receives said mesh incorporating both said anatomical feature and said medical device (C2 40-42), materials properties (material properties/conditions) of said anatomical feature and said medical device, and load (loading conditions) on said anatomical feature and/or said medical

device, and simulates stresses, strains, and deformations of said medical device (C1 L65-68, C2 L1-2 and C2 L59-68 and C3 L1-15). *The in vitro feature is inherent to Berchem et al. (by definition an in vitro feature is a feature in an artificial environment rather than inside a living organism; the environment of the feature does not affect the system taught by Berchem et al.).*

Regarding claims 2, 17 and 32 Berchem et al. discloses a system as where said geometric model of said anatomical feature is an idealized geometric model (Fig 6, element 39 and C4 L58).

Regarding claims 3, 18, 56, and 72 Berchem et al. discloses a system where said three-dimensional volumetric data are acquired via CT scan (C4 L46).

Regarding claims 8, 23, 61, and 77 Berchem et al. discloses a system where said geometry generator is MIMICS. Berchem et al. does not specify that the geometry generator is MIMICS because that is not the preferred embodiment, however it is also well known in the art to use MIMICS to automatically generate contours/polylines to fit b-spline surfaces and objects. Is an option of the designer to choose one of many geometry generators frequently utilized in the art.

Regarding claims 14, 29, 41, 52, 68, 84, 97 and 110 Berchem et al. discloses a system further comprising visualization tool that receives said stresses and strains on said medical device and anatomical feature and displays said stresses and strains on said medical device via visual representation (C4 L52-63, prosthesis model output 36 from the computer).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 4, 19, 57, and 73 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berchem et al. U.S Patent No. 5,150,304 in view of Reisfeld U.S. Patent No. 6,301,496.

Regarding claims 4,19,57, and 73 Berchem et al. discloses all the limitations of the base claims. But, Berchem et al. fails to clearly specify the MRI.

However, Reisfeld discloses a system where said three-dimensional volumetric data are acquired via MRI (Reisfeld, C1 L65-66). Berchem et al. discloses a "Radiation Detector 33" to acquire three-dimensional volumetric data, many data acquiring devices are known in the art. Berchem et al. utilizes CT scan but other devices such as the MRI are known in the art to acquire data (Reisfeld, C1 L65-66).

Therefore at the time the invention was made, it would have been obvious to a person of ordinary skill in the art to modify the above invention suggested by Berchem et al. and combining it with the invention disclosed by Reisfeld. The results of this combination would lead to virtual prototyping and testing for medical device development.

One of ordinary skill in the art would have been motivated to do this modification because many data acquiring devices are known in the art. Berchem et al. utilizes CT scan but other devices such as the MRI are also known in the art to acquire data (Reisfeld, C1 L65-66).

8. Claims 5-7, 20-22, 33-35, 44-46, 58-60, 74-76, 90 and 101-103 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berchem et al. U.S Patent No. 5,150,304 in view of Leotta et al., "Cross-Sectional Area Changes in Peripheral Vein Grafts Monitored by Three-Dimensional Ultrasound Imaging"; 2000 IEEE Ultrasonic Symposium; 5/2000; pages 1865-1868.

Regarding claims 5, 20, 33, 44, 58, 74 and 101 Berchem et al. discloses all the limitations of the base claims. But, Berchem et al. fails to clearly specify details regarding the endovascular prosthesis.

However, Leotta et al. discloses the geometric model of a said medical device is for an endovascular prosthesis (Page1865 'Figure 3')

Although the Berchem et al. reference primarily discusses applications for bones that is just a preferred embodiment of Berchem et al. It is known in the art to design an endovascular prosthesis utilizing the same steps/equipment disclosed by Berchem et al.

Therefore at the time the invention was made, it would have been obvious to a person of ordinary skill in the art to modify the above invention suggested by Berchem et al. and combining it with the invention disclosed by Leotta et al.

One of ordinary skill in the art would have been motivated to do this modification because it is well known in the art to use the Berchem et al. invention in other applications.

Reagrding claims 6, 21, 34, 45, 59, 75, and 102 Berchem et al. in combination with Leotta et al. further disclosea the where said endovascular prosthesis is a transluminally placed endovascular graft (Leotta et al., Page1865 'Figure 3').

Regarding claims 7, 22, 35, 46, 60, 76, 90, and 103 Berchem et al. in combination with Leotta et al. further disclose a system where said endovascular prosthesis is a cardiovascular stent device (implicitly disclosed by Leotta et al.).

9. Claims 9, 24, 36,47, 62, 78, 91 and 104 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berchem et al. U.S Patent No. 5,150,304 in view of Bossart et al., "Finite Element Analysis of Human Joints"; IEEE Signal Process Society, September/1996; pages 1-2.

Regarding claims 9, 24, 36,47, 62, 78, 91 and 104 Berchem et al. discloses all the limitations of the base claims. But, Berchem et al. fails to disclose the TRUEGRID.

However, Bossart et al. discloses a system where said mesh generator is TRUEGRID (Page 9, third paragraph).

Berchem et al. does not specify that the mesh generator is TRUEGRID because that is not the preferred embodiment, however many mesh generators are well known in the art. It is well known in the art to utilize TRUEGRID as a general purpose mesh generation program in order to provide for parameterization capabilities.

Therefore at the time the invention was made, it would have been obvious to a person of ordinary skill in the art to modify the above invention suggested by Berchem et al. and combining it with the invention disclosed by Bossart et al.

One of ordinary skill in the art would have been motivated to do this modification because it is well known in the art to utilize TRUEGRID as a general purpose mesh generation program in order to provide for parameterization capabilities.

10. Claims 10, 11, 15, 25, 26, 30, 37, 38, 42, 48, 49, 53,63, 64, 67, 69, 79, 80, 83, 89, 92, 93, 96, 98, 105, 106, 109, and 111 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berchem et al. U.S Patent No. 5,150,304 in view of Dovey et al. "Finite Element Analysis Results Visualization for Unstructured Grids"; Lawrence Livermore National Laboratory, October/1993; page 4.

Regarding claims 10, 11, 25, 26, 37, 38, 48, 49, 63, 64, 67, 87, 79, 80, 83, 92, 93, 96, 105, 106, and 109 Berchem et al. discloses all the limitations of the base claims. But, Berchem fails to clearly specify the NIKE3D and the DYNA3D.

However, Dovey et al. discloses a system where said stress/strain/deformation analyzer is DYNA3D/NIKE3D(Page 4, first paragraph).

Berchem et al. does not specify that the stress/strain/deformation analyzer is DYNA3D/NIKE3D because that is not the preferred embodiment , however it is known in the art that DYNA3D/NIKE3D is an explicit finite element program for structural/continuum mechanics and dynamic situations.

Therefore at the time the invention was made, it would have been obvious to a person of ordinary skill in the art to modify the above invention suggested by Berchem et al. and combining it with the invention disclosed by Dovey et al.

One of ordinary skill in the art would have been motivated to do this modification because it is known in the art that DYNA3D/NIKE3D is an explicit finite element program for structural/continuum mechanics and dynamic situations.

Regarding claims 15, 30, 42, 53, 69, 89, 98, and 111, Berchem et al. in combination with Dovey et al. further discloses a system where said visualization tool is GRIZ. Berchem et al. does not specify that the visualization tool is GRIZ because that is not the preferred embodiment, however many visualization tools are well known in the art as disclosed by Dovey et al. (Page 4, first paragraph).

11. Claims 12, 13, 27, 28, 39, 40, 50, 51, 65, 66, 81, 82, 94, 95, 107 and 108 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berchem et al. U.S Patent No. 5,150,304 in view of Dovey et al. "Finite Element Analysis Results Visualization for Unstructured Grids"; Lawrence Livermore National Laboratory, October/1993; page 4 and further in view of Holzapfel et al., "Large strain analysis of soft biological membranes: Formulation and finite element analysis, Elsevier Science; October 1995, page 45-61.

Regarding claims 12, 13, 27, 28, 39, 40, 50, 51, 65, 66, 81, 82, 94, 95, 107 and 108 Berchem et al. in combination with Dovey et al. disclose all the limitations of the base claims.

But, Berchem et al. in combination with Dovey et al. fail to clearly specify the stress strain density.

However Holzapfel et al. discloses a system where said DYNA3D is modified to accommodate a strain energy density.

Berchem et al. in combination with Dovey et al. do not specify that DYNA3D is modified to accommodate the equation of the strain energy density because that was not the preferred embodiment however strain energy density equations/models are frequently utilized in the art as disclosed by Holzapfel et al. It is known in the art engineering that when designing it is necessary to generate or alter an equations/models in order to represent situation being analyzed. It is also known that there are many linear and non-linear equations/models to choose from. When simulating behavior of vessels strain energy density equations/models are utilized as disclosed by Holzapfel et al. The Poisson's ratio is frequently applied in the art for obtaining the ratio of transverse contraction strain to longitudinal extension strain in the direction of stretching force. The bulk modulus given as function of Poisson's ratio is known in the art when relating to material. The strain energy density incorporating invariants of the right Cauchy-Green strain tensor is known in the art for representing materials, as disclosed by Holzapfel et al. This is because the Cauchy-Green strain tensor provides for deformation measures.

Therefore at the time the invention was made, it would have been obvious to a person of ordinary skill in the art to modify the above invention suggested by Berchem et al. and Dovey et al. and combining it with the invention disclosed by Holzapfel et al.

One of ordinary skill in the art would have been motivated to do this modification because as mention above strain energy density equations/models are frequently utilized in the art.

Citation of Pertinent Prior Art

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The following patents are cited to further show the state of the art with respect to virtual prototyping and testing for medical device development

a. U.S. Pat. No. 4,742,464 to Duret et al., which discloses dental prosthesis.

b. U.S. Pat. No. 5,233,992 to Holt et al., which discloses MRI method.

c. U.S. Pat. No. 5,273,038 to Beavin, which discloses simulation of live organ.

d. U.S. Pat. No. 5,365,996 to Crook, which discloses customized fixation device.

e. U.S. Pat. No. 5,506,785 to Blank et al., which discloses representations of volumetric data.

f. U.S. Pat. No. 5,601,084 to Sheehan et al., which discloses cardiac wall thickness modeling.

g. U.S. Pat. No. 5,612,885 to Love, which discloses heart valve stent.

h. U.S. Pat. No. 5,798,924 to Eufinger et al., which discloses endoprostheses.

i. U.S. Pat. No. 6,463,351 to Clynch, which discloses custom fitted medical device.

The following publications are cited to further show the state of the art with respect to virtual prototyping and testing for medical device development:

j. Taylor et al, " Finite Element Modeling of Three-Dimensional Pulsatile Flow in the Abdominal Aorta: Relevance to Atherosclerosis"; Annals of Biomedical Engineering; Vol 26; 1998; pages 975-987.

k. "Predictive Analysis at the Forefront of Medical Product Development"; MD&DI, Oct/1999.

l. Rebelo et al.; "Finite element analysis for the design of Nitinol medical devices"; Pacific Consultants; 1999.

m. Maker et al.; "NIKE3D, A nonlinear, implicit, three-dimensional finite element code for solid and structural mechanics user's manual"; April 14, 1995.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlos Ortiz-Rodriguez whose telephone number is (703) 305-8009. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Leo P. Picard can be reached on (703) 308-0538. The central official fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-3900.

Carlos Ortiz-Rodriguez
Patent Examiner
Art Unit 2125

cror

August 19, 2004

LEO PICARD
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